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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,337	05/09/2006	Seong Hwan Cho	1751-0400	8934
6449 7590 04/25/2011 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER				
ROYDS, LESLIE A				
ART UNIT		PAPER NUMBER		
1629				
NOTIFICATION DATE		DELIVERY MODE		
04/25/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/574,337

**Applicant(s)**

CHO ET AL.

**Examiner**

Leslie A. Royds Draper

**Art Unit**

1629

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 19 April 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because:  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
 NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).  
 4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-16.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Leslie A. Royds Draper/  
Primary Examiner, Art Unit 1629

## Continuation of 3. NOTE:

Applicant's proposed after-final amendment filed April 19, 2011 will not be entered into the record because the proposed amendments to claim 1 raise new issues that would require further consideration and/or search.

In particular, Applicant proposes amending instant claim 1 to now recite that the sustained-release formulation comprises an optional outer coating layer coated on the active ingredient-containing film coating layer and comprising a film coating polymer selected from the group consisting of a hydrophilic polymer, a hydrophobic polymer, a pH-dependent polymer and a combination thereof, which is a new limitation that was not previously considered and/or searched during the course of prosecution. In addition, Applicant also proposes limiting the formulation to a three or four layer tablet wherein the three or four layers are as defined in parts (a)-(d) of claim 1, when the claims as previously presented were directed to at least three layers in the tablet. These are new issues that require further consideration and/or search and, as a result, will not be entered into the record.

Because the proposed amendments clearly raise new issues that would require further consideration and search, the amendments will not be entered into the record. In addition, the proposed claim amendments are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal because they raise new issues that require further consideration and/or search.

## Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's request for reconsideration of the present application with regard to the rejections of record under 35 USC 112p1 and 103 in light of the amendments to the claims proposed and presented in the after-final amendment dated April 19, 2011 has been made. In light of the fact that the proposed amendments to the claims will not be entered into the record, Applicant's remarks directed to the obviation of the rejections under 35 USC 112p1 and 103 due to the limitation of the claimed formulation as a "3 or 4 layer tablet" are not found persuasive.

Insofar as the remarks provided in response to the written description rejection under 35 USC 112p1 apply to the previously pending set of claims, such remarks will be herein considered. Applicant traverses the rejection under 35 USC 112p1 regarding the limitation of part (a) of claim 1, i.e., "a sustained-release core comprising a mixture of an active ingredient and a polymer having erosion and swelling property in mammalian intestinal secretions". Applicant states that the specification provides written description of a sustained-release core comprising the active ingredient and the specified polymer and submits that he was in possession of a mixture of the active ingredient and the specified polymer because such ingredients must be in a mixture in order for the core to comprise the recited ingredients.

The remarks are unpersuasive. The disclosure that the sustained-release core may comprise the active ingredient and the specified polymer circumscribes any physical arrangement of the two components within the core, i.e., layers, homogenous mixture, etc. The sole disclosure of a clear "mixture" of the two components (i.e., the active ingredient and the specified polymer) as now claimed is present only at p.10 of the instant specification, wherein the specification describes the core comprising the active ingredient, a swellable polymer, a direct compression diluent and a disintegrating agent that are specifically mixed when direct compression or compaction-granulation are used. These particular conditions of the manner in which the core is formed (i.e., direct compression, compaction-granulation, etc.) or the other components to make such a mixture as disclosed are not recited in the rejected claims. As a result of this omission, the claims circumscribe a broader scope of subject matter than what was originally disclosed in the specification and claims as originally filed and, thus, remain properly rejected.

For these reasons, the proposed amendments to the claims will not be entered. The claims remain objected to and/or rejected for the reasons previously set forth in the final rejection dated January 26, 2011, of which said reasons are herein incorporated by reference but are not repeated in the interest of brevity.

/Leslie A. Royds Draper/  
Primary Examiner, Art Unit 1629